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FIRST NAMED INVENTOR APPLICATION NO. **FILING DATE** ATTORNEY DOCKET NO. Н 026083/0195 HEIDTMANN 09/256,237 02/24/99 **EXAMINER** HM12/0615 SUN HOFFMAN, L FOLEY & LARDNER SUITE 500 **ART UNIT** PAPER NUMBER 3000 K STREET NW 1642 WASHINGTON DC 20007-5109 DATE MAILED: 06/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

### Office Action Summary

Application No. **09/256,237** 

Applicam(S)

Heinrich et al

Examiner

Lin Sun-Hoffman

Group Art Unit 1642



Responsive to communication(s) filed on	
☐ This action is <b>FINAL</b> .	
☐ Since this application is in condition for allowance except for formal matters, prosection in accordance with the practice under Ex parte Quay/1935 C.D. 11; 453 O.G. 213.	cution as to the merits is closed
A shortened statutory period for response to this action is set to expire1 month longer, from the mailing date of this communication. Failure to respond within the period for application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained 37 CFR 1.136(a).	or response will cause the
Disposition of Claim	
X Claim(s) <u>1-25</u>	is/are pending in the applicat
Of the above, claim(s)	is/are withdrawn from consideration
Claim(s)	is/are allowed.
☐ Claim(s)	is/are rejected.
☐ Claim(s)	is/are objected to.
	at to restriction or election requirement.
Application Papers  See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed on is/are objected to by the Examiner.  The proposed drawing correction, filed on is approved  The specification is objected to by the Examiner.  The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. § 119  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(a)  AllSome* None of the CERTIFIED copies of the priority documents hav received.  received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT *Certified copies not received: Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e)	□disapproved.  d).  ve been  Rule 17.2(a)).
Attachment(s)  Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152 September 40 Covpt with Septe	

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#### **DETAILED ACTION**

#### Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-18, 20, 22, 24 drawn to a nucleic acid construct, classified in class 536, subclass 23.1.
  - II. Claims 21, 23, 25, drawn to a protein and a method of preparation, classified in class 530, subclass 350+.
  - III. Claim 19, drawn to a method of treatment, classified in class 424, subclass 44.
- 2. The inventions are distinct, each from the other because of the following reasons:

  Inventions I-II as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions. Inventions I and II are unrelated because the polynucleotides of invention I can be used in hybridizations assay whereas the inventions of II cannot, the proteins of invention II can be used in affinity purification schemes ant to make antibodies whereas the polynucleotides of invention I cannot.

The inventions of Groups I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see MPEP § 806.05(h)].

In the instant case, nucleic acid in invention I as claimed can be used in a materially different process such as a DNA ladder, whereas invention III cannot. The proteins of invention

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II can be used to make antibodies, whereas the invention III cannot. However, the invention III can be used by chemotherapy, whereas the inventions I and II cannot.

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Claims 1-18 are generic to a plurality of disclosed patentably distinct species comprising 3. an active compound functions as an activator or inhibitor in the specific biological process (elect one specific function of the active compound in claim 12), wherein the active compound is of different factors (elect one specific factor that the construct encodes in claim 13); a ligand (elect one in claims 14 and 15). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- Applicant is reminded that upon the cancellation of claims to a non-elected invention, the 4. inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- Due to the complexity of this restriction, a telephone call to request an oral election to the 5. above restriction requirement was not made.

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6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

#### Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lin Sun-Hoffman, Ph.D., who can be reached on (703) -308-4301.

Lin Sun-Hoffman, Ph.D.

June 13, 2000

NANCY A. JOHNSON, PH.D. PRIMARY EXAMINER

09/256,237

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# NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

<ol> <li>This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.</li> </ol>	
2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).	
3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).	
4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."	
5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).	
6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).	
7. Other: Applicant should follow the format of the attached sample statement to request that the CRF filed in the parent application be used to create a CRF in this application.	
Applicant Must Provide:	
An <u>initial</u> or substitute computer readable form (CRF) copy of the "Sequence Listing".	
An <u>Initial</u> or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.	
A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).	
For questions regarding compliance to these requirements, please contact:	
For Rules Interpretation, call (703) 308-4216	
For CRF Submission Help, call (703) 308-4212	
For Patentin software help, call (703) 308-6856  PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE	
I LLAUL INCLUING A CUPT UP THIS NOTICE WITH YOUR RECOONCE	

## Sample Statement

Sample Request to Use Computer Readable orm from Another Application

The following paragraph, or language having the same effect, can be used to invoke the procedures of 37 CFR section 1.821(e) in which an identical computer readable form from another application is used in a given application. The paragraph should be incorporated into a separate paper to be submitted in the given application:

The computer readable form in this application, 08/100,000, is identical with that filed in Application Number 07/999,999, filed March 1, 1988. In accordance with 37 CFR 1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the patent and Trademark Office will make the necessary change in application number and filing date for the computer readable form that will be used for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].